

CIBINQO[™]
(abrocitinib) tablets



What tests will go along with treatment?

CIBINQO is a prescription medicine for people 12 years and older with moderate-to-severe eczema (atopic dermatitis) who didn't respond to previous treatment and when other treatments, including oral or injected medicines, haven't worked well or are not right for them.

IMPORTANT SAFETY INFORMATION

CIBINQO may cause serious side effects, including:

Serious infections. CIBINQO can lower your immune system's ability to fight infections. Do not start CIBINQO if you have any kind of infection unless your healthcare provider tells you it is okay. Serious infections, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that can spread throughout the body, have occurred in people taking CIBINQO or other similar medicines. Some people have been hospitalized or died from these infections. Your risk of developing shingles may increase while taking CIBINQO.

Your healthcare provider should test you for TB before treatment with CIBINQO and monitor you closely for signs and symptoms of TB infection during treatment.

*Please see additional Important Safety Information throughout. Please click for full Prescribing Information, including **BOXED WARNING**, and Medication Guide or visit [CIBINQO.com](https://www.cibinqo.com).*

Before starting CIBINQO

In addition to evaluating overall health and medical history to determine if CIBINQO is right for you or your teen, your doctor will also order blood tests.

What tests will my doctor perform to help determine if CIBINQO is the right option?

Your doctor will perform a few tests, including:

- **Checking a complete blood count (CBC)**
- **Screening for infections, including tuberculosis (TB) and hepatitis B and C**

Your doctor will also check to ensure your vaccines are up to date.

Why do I need to take these tests?

You should not take CIBINQO if your blood cell counts are too low, or if you have active TB, hepatitis B or C, or serious infection. If needed, your doctor may stop your CIBINQO treatment for a period of time because of changes seen in your blood test results. Your doctor should also check your cholesterol levels to see if the amount of fat in your blood has increased.

How often will I be tested?

- **Before starting treatment**
- **Four weeks after starting CIBINQO**
- **Four weeks after any increase in dose**

Based on your health and medical history, your doctor may order other blood tests as needed.

IMPORTANT SAFETY INFORMATION (cont'd)

Before and after starting CIBINQO, tell your doctor right away if you have an infection, are being treated for one, or have symptoms of an infection, including: fever, sweating, or chills; muscle aches; cough or shortness of breath; blood in your phlegm; weight loss; warm, red, or painful skin or sores on your body; diarrhea or stomach pain; burning when you urinate or urinating more often than usual; or feeling very tired.

CIBINQO can make you more likely to get infections or worsen infections you have. If you get a serious infection, your healthcare provider may stop treatment with CIBINQO until your infection is controlled.

While taking CIBINQO

After starting CIBINQO, your doctor will continue to monitor your health.

This includes, but is not limited to:

- **Monitoring you for signs and symptoms of infections, including TB and hepatitis B and C**
- **Checking for changes in blood cell counts and cholesterol levels**
- **Performing periodic skin checks, as there is an increased risk of skin cancer with JAK inhibitors**

Notes

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IMPORTANT SAFETY INFORMATION (cont'd)

There is an increased risk of death in people 50 years and older who have at least one heart disease (cardiovascular) risk factor and are taking a Janus kinase (JAK) inhibitor (such as CIBINQO).

Cancer and immune system problems. CIBINQO may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers, can happen. People, especially current or past smokers, have a higher risk of certain cancers, including lymphoma and lung cancers, while taking a JAK inhibitor. Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment. Limit the amount of time you spend in sunlight and avoid using tanning beds or sunlamps. When in the sun, wear protective clothing and use SPF 30+ sunscreen. This is especially important if you have very fair skin or a family history of skin cancer. Tell your healthcare provider if you have ever had any type of cancer.

There is an increased risk of major cardiovascular (CV) events such as heart attack, stroke or death in people 50 years and older who have at least one heart disease (CV) risk factor and are taking a JAK inhibitor, especially for current or past smokers.

Some people taking CIBINQO have had major cardiovascular events.

Get emergency help right away if you develop any symptoms of a heart attack or stroke while taking CIBINQO, including: discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw, or stomach; weakness in one part or on one side of your body; slurred speech; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; or feeling lightheaded.

Blood clots. Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking CIBINQO. This may be life-threatening. Blood clots in the veins of the legs and lungs have happened more often in people 50 years and older, with at least one heart disease (CV) risk factor, taking a JAK inhibitor. Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past.

Stop taking CIBINQO and get medical help right away if you have any signs and symptoms of blood clots including swelling, pain, or tenderness in one or both legs; sudden, unexplained chest or upper back pain; shortness of breath or difficulty breathing.

Changes in certain laboratory test results. Your doctor should do blood tests before and during treatment with CIBINQO to check your lymphocyte, neutrophil, red blood cell, and platelet counts. You should not take CIBINQO if these counts are too low. Your healthcare provider may stop treatment for a period of time if there are changes in these blood test results.

Increased cholesterol levels. You may also have increases in the amount of fat found in your blood. Your doctor should check your cholesterol about 4 weeks after you start CIBINQO and then as needed.

During the first 3 months of treatment with CIBINQO, do not take medicines that prevent blood clots except low-dose aspirin (≤ 81 mg daily), if prescribed.

Before taking CIBINQO, tell your healthcare provider if you:

- have an infection, are being treated for one, or have one that won't go away or keeps returning
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have TB or have been in close contact with someone with TB

- have had shingles (herpes zoster)
- have had hepatitis B or hepatitis C
- live, have lived, or traveled to certain areas (such as Ohio & Mississippi River Valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or worsen when taking CIBINQO. Ask your healthcare provider if you're unsure if you have lived in an area where these infections are common
- have had any type of cancer
- have had blood clots in the veins of your legs or lungs
- are a current or past smoker
- have had a heart attack, other heart problems, or stroke
- have kidney or liver problems
- have abnormal blood tests (low platelet count or white blood cell count)
- have high levels of fat in your blood (high cholesterol)
- have any eye problems, including cataracts or retinal detachment
- have recently received or are scheduled to receive any vaccinations. People who take CIBINQO should not receive live vaccines
- are or plan to become pregnant. It is not known if CIBINQO will harm your unborn baby. Pfizer has a **Pregnancy Exposure Registry** for pregnant women who take CIBINQO to check your health and the health of your baby. If you are pregnant or become pregnant while taking CIBINQO, ask your healthcare provider how you can join this pregnancy registry, call **1-877-311-3770**, or visit www.CIBINQOPregnancyRegistry.com to enroll
- are breastfeeding or plan to breastfeed. It is not known if CIBINQO passes into your breast milk. You should not take CIBINQO while breastfeeding
- are taking other medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements. CIBINQO and other medicines may affect each other, causing side effects. **Especially tell your healthcare provider if you take aspirin or any antiplatelet therapies.** Ask your healthcare provider if you are unsure

The most common side effects of CIBINQO include common cold, nausea, headache, herpes simplex including cold sores, increased blood level of creatine phosphokinase, dizziness, urinary tract infection, tiredness, acne, vomiting, mouth and throat pain, flu, stomach flu, bacterial skin infection, high blood pressure, allergic skin rash to something you contacted, stomach pain, shingles, and low platelet count.

Separation or tear to the lining of the back part of the eye (retinal detachment) has happened in people treated with CIBINQO. Call your healthcare provider right away if you have any sudden changes in your vision.

CIBINQO may cause fertility problems in females, which may affect the ability of females to get pregnant. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of CIBINQO.

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**ONE PILL
ONCE A DAY**

100% steroid free | Not an injection or cream

For more information, visit [CIBINQO.com](https://www.cibinqo.com)

What is CIBINQO?

CIBINQO is used to treat adults and children 12 years of age and older with moderate-to-severe eczema (atopic dermatitis) that did not respond to other treatment and is not well controlled with prescription medicines, including biologics, or when they cannot be tolerated.

It is not known if CIBINQO is safe and effective in children under 12 years of age.

You are encouraged to report adverse events related to Pfizer products by calling **1-800-438-1985** (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit www.fda.gov/MedWatch or call **1-800-FDA-1088**.

CIBINQO is available in 50 mg, 100 mg, and 200 mg pills.

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